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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,347

Applicant(s)

BENOWITZ, LARRY I.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8,12-34 and 38-46 is/are pending in the application.
- 4a) Of the above claim(s) 3,7,32-34 and 38-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6, 8, 12-31, and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 13 on June 2, 2003 has been entered in full. Claims 2, 5, 9-11, and 35-37 have been canceled. Claims 1, 4, 12, 14-18, and 25 have been amended. Claims 1, 3, 4, 6-8, 12-34, and 38-46 are pending. Claims 1, 4, 6, 8, 12-31, and 44-46 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Objections and/or Rejections

Applicants' cancellation of claims 2, 5, 9-11, and 35-37 has made the rejections and objections related to these claims, as set forth in Paper No. 12, moot.

The rejection of claims 15-17 under 35 U.S.C. § 112, first paragraph for enablement, as set forth at page 5-7 in Paper No. 12, has been withdrawn in view of Dr. Benowitz's Declaration.

The rejection of claims 1, 4, 6, 8, and 12-31 are rejected under 35 U.S.C. 112, first paragraph for Written Description, as set forth at pages 7-8 in Paper No. 12, has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 1, 4, 6, 8, and 12-31 under 35 U.S.C. §112, second paragraph, as set forth at page 8 in Paper No. 12, has been withdrawn in view of Applicants' amendment to the claims.

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The rejection of claims 1, 12, 14, 18, 27, and 30 under 35 U.S.C. 102(b) as being anticipated by Flanders et al. (Prog. Neurobiolo. 54:71-85, 1998), as set forth at page 9 in Paper No. 12, has been withdrawn in view of Applicants' amendment to the claims.

III. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph (Scope Enablement)

The rejection of claims 1, 6, 8, 12-14, 18-28 under 35 U.S.C. § 112, first paragraph for Scope enablement, as set forth at pages 3-5 in Paper No. 12, remains.

The amended claims 4 and 15-17 are also rejected under 35 U.S.C. § 112, first paragraph for Scope enablement.

Claim 1 recite "a subject having a neuronal injury". Claims 6, 8, 12-14, and 15-28 depend upon claim 1, either directly or indirectly. However, the specification and the Declaration by Dr. Benowits only disclose a method of comprising administering to a subject therapeutically effective amount of oncomodulin by introduction into a region of *neuronal injury of retinal ganglion cells* and producing an effect on neuronal survival, regeneration, and axonal outgrowth. It is noted that only "neuronal injury of retinal ganglion cells", not the generic term, "neuronal injury", is enabled. The specification fails to provide any sufficient guidance and working examples regarding the neuroprotective effects on neuronal injury of *any other types of neurons*.

The amended claim 4 recite a non-hydrolyzable cAMP analogue. However, Dr. Benowitz's Declaration only shows that one non-hydrolyzable cAMP analogue, dBcAMP, when used together with oncomodulin, caused many RGCs to regenerate their axons through the optic nerve. There is no sufficient guidance provided teaching how to extrapolate this single example to predict which of the many non-hydrolyzable

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cAMP analogues would be reasonably expected to have a similar effect in this system. In fact, a nonhydrolyzed analogue of cAMP, sp-8-Br-cAMPs, was shown to be inactive in inducing axon outgrowth by Iorio et al. (IDS, Drug Development Research 52:303-315, 2001; see especially Fig. 1).

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph (Enablement)

The rejection of claims 29-31, and 44-46 under 35 U.S.C. § 112, first paragraph for enablement, as set forth at pages 5-7 in Paper No. 12, remains.

Applicants argue that the Declaration by Dr. Lary Benowitz demonstrates, in an in vivo model, that oncomodulin can stimulate mature rat RGCs to regenerate their axons through an injured optic nerve crush. Applicants also argue that this model is a standard in the field for the treatment of neuronal injury.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the Declaration by Dr. Lary Benowitz says nothing about treatment of neurological disorders other than neuronal injury of retinal ganglion cells. Neither the Declaration by Dr. Lary Benowitz nor the specification fails to show how the claimed methods comprising administering oncomodulin would be used for treating neurological disorders, such as a spinal cord injury or Alzheimer's disease (page 5 of specification. There are not sufficient guidance and working examples on teaching treatment of neurological disorders other than neuronal injury of retinal ganglion cells. Due to complexity of the nature of neurological disorders, it is unpredictable whether a given neurological disorder, such as Alzheimer's disease, can be successfully treated by oncomodulin.

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V. Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
August 7, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600